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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,089	09/24/2001	Shahzi Iqbal		7293

34456 7590 01/16/2004

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT PAPER NUMBER

1637

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/961,089

Applicant(s)

CHIN ET AL.

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,27,29-41 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27,29-33,36,38-40 and 43-45 is/are allowed.
- 6) ☒ Claim(s) 35 and 37 is/are rejected.
- 7) ☒ Claim(s) 26,34,35,41,46 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 10, 2003 has been entered.

Status of the Application

2. This action is in response to Applicants' request for continued examination, filed on October 10, 2003. Currently, claims 26-27, 29-41 and 43-47 are pending, Claims 35 and 47 are rejected herein. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, the claim objections, 112, 2nd paragraph, 102 and 103 rejections (over Sytkowski and Sytkowski, in view of Zeng, respectively) have been withdrawn in view of Applicants amendments. Specifically, with respect to the 102 and 103 rejections, Sytkowski does not teach, "degrading the cDNA/RNA complements *to leave the unhybridized cDNA strands and the unhybridized RNA strands*". This action is made NON-FINAL.

Disclosure/Claim Objections

3. The claims are objected to because of the following informalities:

A) Claims 26, 34-35, 41 and 46-47 recite, "compliments", which should be amended to recite, "complements".

This change can be made to the specification as well, where appropriate, (e.g., see pages 6-7).

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B) Claim 41 recites, "remaning", which should recite, "remaining".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st Paragraph (Enablement)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

MPEP 2164.01 states:

Even though the statute does not use the term 'undue experimentation,' it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)

The *Wands* court outlined several factors to be considered in determining whether a disclosure would require undue experimentation. These factors include, but are not limited to:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 1404.

In the instant case, the specification does not enable one of skill in the art to make and use the claimed invention for the following reasons:

(1) Nature of the Invention & Breadth of the Claims

The claims are drawn to a method for eliminating redundant sequences that are common between two samples and a method for determining differences between a first sample of cDNA strands and a second sample of RNA strands, wherein cDNA/RNA complements are degraded and unhybridized cDNA and unhybridized RNA strands are left. The unhybridized cDNAs and RNAs are single stranded (ss). Claims 35 and 47 are drawn to using Exonuclease VII for degrading the cDNA/RNA complements.

(2) Relative Skill of those in the Art, State of the Prior Art, Amount of Direction or Guidance Presented & Presence or Absence of Working Examples

As stated above, Claims 35 and 47 are drawn to degrading cDNA/RNA compliments using Exonuclease VII. However, Exonuclease VII is an enzyme that does not degrade cDNA/RNA complements, but is an enzyme that digests single stranded DNA. This is exemplified in the teachings of Sytkowski et al., who states "a DNA nuclease which digests single-stranded DNA molecules...is selected from the group consisting of mung bean nuclease, exonucleases VII...". (See USPN 5,804,382, col. 2, lines 52-56, previously cited)

The specification also only provides guidance that Exonuclease VII digests single stranded DNA. Specifically, in Example 2, the specification states, "the other embodiment is the Exonuclease VII (digests ssDNA)". Furthermore, Figure 2, states, "Add Exonuclease VII, degrades all ss cDNA". The specification does not provide any guidance or teaching that Exonuclease VII degrades cDNA/RNA complements. The specification teaches Example 4,

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entitled, "Exonuclease VII Approach", however, this example does not demonstrate that cDNA/RNA complements were actually degraded by the Exonuclease VII.

The prior art is also silent as to using Exonuclease VII for digesting cDNA/RNA complements. Accordingly, the relative skill in molecular biology for determining sequence differences and eliminating redundant sequences by degrading cDNA/RNA complements using Exonuclease VII is high, since the art does not teach that Exonuclease VII has this property.

Therefore, the relative skill in the art is high, the state of the art is silent as to degrading cDNA/RNA complements with Exonuclease VII, and the specification does not provide the requisite guidance or working examples that demonstrate that Exonuclease VII degrades cDNA/RNA complements.

(3) Quantity of Experimentation Necessary & the Unpredictability of the Art

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. In *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art.

In the instant case, the prior art, nor the specification, teach that Exonuclease VII degrades cDNA/RNA complements. Due to this lack of guidance in the specification and the art, the experimentation required by the skilled artisan would be considered undue. That is, the experimentation to determine this property (i.e., that Exonuclease VII degrades cDNA/RNA

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complements) requires a trial and error analysis, with little to no starting point, absent any teaching in the specification or the art. In fact, the art actually teaches away from using Exonuclease VII for degrading double stranded complexes, and teaches that it is a single stranded specific nuclease (see above). Therefore, the utility of using Exonuclease VII for degrading cDNA/RNA complements would be considered unpredictable, and is therefore considered undue.

In essence, the experimentation that one skilled in the art would be required to perform is in fact the proposed novelty of the invention. However, "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001).

Accordingly, in view of the unpredictability in the art and in view of the lack of specific disclosure in the specification, undue experimentation would be required to practice the invention as it is claimed.

Conclusion

5. Claims 26-27, 29-41 and 43-47 are free of the prior art.

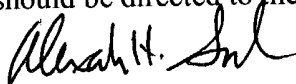
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806 or (571) 272-0788 after January 22, 2004. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

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If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199 or at (571) 272-0747 after January 13, 2004. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119 or at (571) 272-0782 after January 22, 2004. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alexander H. Spiegler
January 9, 2004



JEFFREY SIEW
PRIMARY EXAMINER

1/9/04